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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/676,869

09/30/2003

Hassan Serhan

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7992

27777 7590 04/13/2007
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EXAMINER

REIMERS, ANNETTE R

ART UNIT

PAPER NUMBER

3733

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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3 MONTHS

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/676,869

Applicant(s)

SERHAN ET AL.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/27/06.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Invention I, claims 1-7 and 11-15 in the reply filed on January 26, 2007 is acknowledged. The traversal is on the ground(s) that there would not be a significant burden on the examiner. This is not found persuasive because, "a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification" (see M.P.E.P. § 808.02). In the instant case, as stated in the election/restriction, inventions I and II are unrelated. Invention I is drawn to a minimally invasive method of augmenting or replacing the nucleus pulposus of a spinal disc, whereas invention II is drawn to a method of preparing a small intestine submucosa implant. These two distinct methods require different steps and have different applications and results. Therefore, a divergent search would be required for each method. The requirement is still deemed proper and is therefore made FINAL.

Claims 8-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on January 26, 2007.

Claim Objections

Claims 12-15 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only--,

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and/or, -- cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 12-15 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6, line 1, "the form of elongated material" lacks proper antecedent basis.

In claim 7, "the elongated form" lacks proper antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5-7 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (U.S. Patent Publication Number 2003/0195630).

Ferree discloses a minimally invasive method of augmenting or replacing the nucleus pulposus of a spinal disc comprising the steps of preparing a disc treatment site, piercing and inserting into and through the sidewall of the disc's annular ring a cannulated insertion tool and inserting an elongated nucleus pulposus augmentation or replacement material through the cannulated insertion tool and into the nucleus

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pulposus, wherein the elongated nucleus pulposus augmentation or replacement material is selected from strips, cords, braids, tubes, rolls and pellets, and further comprising the presence of a bioactive factor in the elongated nucleus pulposus augmentation or replacement material (see figures 1-7C and paragraphs 0006, 0019 and 0021).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (U.S. Patent Publication Number 2003/0195630) in view of Kennedy, II et al. (U.S. Patent Publication Number 2005/0113855).

As stated above, Ferree discloses a minimally invasive method of augmenting or replacing the nucleus pulposus of a spinal disc comprising the steps of preparing a disc treatment site, piercing and inserting into and through the sidewall of the disc's annular ring a cannulated insertion tool and inserting an elongated nucleus pulposus augmentation or replacement material through the cannulated insertion tool and into the nucleus pulposus, wherein the elongated nucleus pulposus augmentation or replacement material is selected from strips, cords, braids, tubes, rolls and pellets, and further comprising the presence of a bioactive factor in the elongated nucleus pulposus

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augmentation or replacement material (see figures 1-7C and paragraphs 0006, 0019 and 0021).

Ferree discloses the claimed method except for inserting small intestine submucosa (SIS) through the cannulated insertion tool and into the nucleus pulposus. Kennedy, II et al. disclose the use of SIS as an implant and teach the use of SIS due to its special bio-remodeling characteristics, which make SIS a preferred and successful implant material. It would have been obvious to one skilled in the art at the time the invention was made to include the use of SIS in the method disclosed by Ferree, in view of Kennedy II, et al. due to SIS's special bio-remodeling characteristics, which make it a preferred and successful implant material.

Response to Arguments

Applicant's arguments with respect to claims 1-7 and 11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO 892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ARC


EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER